IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Christine Carlucci and Gerard Carlucci
For:	Medical Tubing Securing Device
Serial No.:	09/930,398
Filed:	August 15, 2001
Group:	3761
Atty Docket:	262.801

APPEAL BRIEF

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February 12, 2007

Real party in interest

Christine Carlucci and Gerard Carlucci

Related appeals and interferences

A first appeal brief was filed on September 9, 2003, appealing the final rejection mailed on April 9, 2003. In response to the appeal brief, a new office action issued on November 28, 2003, treating the appeal brief as a request for reconsideration of the finality of the rejection and withdrawing the finality of the final action. After further prosecution, the examiner issued a final action on May 18, 2004, from which appeal was taken and appellants filed their second appeal brief on October 18, 2004.

On January 11, 2005, the examiner issued an office action in view of the second appeal brief and reopened prosecution which continued until the examiner issued a final rejection on August 19, 2005. The examiner withdrew the final action, whereupon prosecution continued. The examiner then issued a final rejection on July 11, 2006, from which this present, the third, appeal is taken.

Status of claims

Claims 1-14 are all the claims in the case. Claims 1-14 were rejected in the final action mailed on July 11, 2006. Appellants appeal the rejection of claims 1-14.

Status of amendments

No amendment was filed subsequent to the final rejection.

Summary of claimed subject matter

Claim 1 of the present invention reads as follows:

> A device to secure medical tubing to a body comprising a circular one-piece fabric band having a length wherein the band is divided into at least a first closed loop and a second closed loop such that the band is composed of no more than two layers of fabric anywhere along the length, and wherein the first closed loop fits elastically around a portion of the body and the second closed loop is capable of receiving and holding medical tubing close to the body.

All the claims of the application are limited to a one-piece fabric band having a closed loop which fits elastically around a portion of the body.

Referring to FIGS. 1, 2, 4, the device of the claimed invention is denominated by numeral 12. Device 12 is made of a band of an elasticized, absorbent fabric. Device 12 includes a relatively large circular section 15 which will fit snugly to the head of the patient when slipped over the top of the skull. At least one loop 14 is adjacent to section 15, through which medical tubing such as that associated with a CPAP apparatus 10 can be inserted. As shown in FIGS. 2, 3, and 4, loop 14 can be formed by joining two points 16a and 16b, along the width w of the band, such as by stitching 13 or other non-disengagable fastening technique.

As shown by reference to FIG. 1, CPAP apparatus 18 is secured to the head of a patient through use of the device 12. Apparatus 12 extends around the patient's head, above the ears. The tubing portions 10 of the CPAP apparatus are passed through loops 14 and the nasal cannulae 19 are positioned so as to fit into the nose 20 of the patient. There is no danger of the tubing portions pulling away from device 12, since loops 14 are closed. Used as illustrated, device 12 is comfortably yet firmly seated on the patient's head and securely anchors medical tubing to the head, without the need for potentially injurious components.

Prior art devices for securing medical tubing to the head of a hospitalized patient are discussed in the specification at pages 1-2 and in the declarations of Dr. Veniamin Ratner (¶¶ 3-6) and Nurse Terri Lee Maurer (¶¶ 5-7, and attachment A thereto), submitted in this case on May 11, 2005 and attached in the evidence appendix hereto. As pointed out in the specification and in the declarations of Nurse Maurer and Dr. Ratner, there are numerous drawbacks to the various prior art devices. Some are prone to slippage. Attempts to correct slippage include taping the device or the tubing to the head or the face. Such a correction, however, often gives rise to another set of problems, such as allergic reactions to the tape adhesive or skin irritation as a result of tape removal. An alternative to tape is to tighten the apparatus on the patient's head using such accessories as safety pins and rubber bands. *See*, Ratner Decl. ¶ 6, photos 1 and 2 thereto. Such tightening is often inadequate to prevent slippage (*id.*), but in patients such as premature infants, greater tightening can be harmful since their skulls are soft and deformable. Other prior art devices present drawbacks such as inadvertent disassembly of the ties, buckles, or hook-and-eye closures that are utilized to hold and secure the medical tubing.

The claimed device does not irritate the skin, compress the skull or blood vessels, or incorporate bulky or dangerous components which can cause discomfort or injury to the often delicate patients who require the treatments delivered via medical tubing into their compromised bodies. In addition, by virtue of the loops being closed, the tubing cannot disengage from the securing device, thus insuring effective, non-interrupted treatment. The success of the claimed invention in overcoming the drawbacks of the prior art device has earned it accolades from doctors and nurses who care for prematurely born infants having respiratory issues. *See, e.g.,* Mauer Decl. ¶¶ 9, 10; Ratner Decl. ¶¶ 8, 9, photos 3, 4 thereto.

Grounds of rejection to be reviewed on appeal

Whether it was error to reject claims 1-14 as anticipated by United States Patent 5,117,510 to Broussard ("the '510 patent" or "the Broussard patent") when the Broussard patent does not disclose a fabric band divided into at least a first and a second closed loop, which is a limitation in all the rejected claims.

Argument: The Broussard Patent Does Not Disclose the Limitations of a Divided Band or a Closed Loop

The examiner rejected the claims under 35 U.S.C. § 102 as anticipated by US Patent 5,117,510 to Broussard ("the Broussard patent").[1] This rejection was erroneous in that the Broussard patent fails to teach all the essential elements of the claims of the application.

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[1] This was the eighth office action issued on this application, the prosecution having followed an extraordinarily long course. The application was filed on August 15, 2001. A first office action rejecting the claims under § 102 in view of US Patent 6,269,814 to Blaszczkiewicz was mailed on October 29, 2002 to which a response was filed on January 28, 2003. A final rejection issued on April 9, 2003, rejecting the claims under § 103 in view of the Blaszczkiewicz patent, to which an appeal was taken and a brief filed on September 9, 2003. In view of the brief, the final rejection was withdrawn on November 28, 2003, and a further office action issued, this time rejecting the claims under § 102 in view of US Patent 5,411,484 to Shattuck, and under § 103 in view of the Shattuck patent taken with US Patent 3,878,849 to Muller. Applicants filed a response to that office action on February 25, 2004. A final rejection then issued on May 18, 2004, rejecting the claims under § 102 in view of the Shattuck patent taken with a new reference, US Patent 5,154,690 to Shiono. Applicants filed an appeal brief on October 18, 2004. In view of the appeal brief, the examiner reopened prosecution on January 1, 2005, and issued an office action, rejecting the claims under § 102 in view of the Shattuck patent, further under § 102 in view of US Patent 4,723,325 to Perry, and under § 103 in view of the Shattuck patent taken with the Muller patent. Applicants responded to the office action on May 11, 2005. The examiner issued a final rejection on the claims on August 19, 2005, withdrawing the previous rejections and citing new grounds, US Patent 5,446,953 to LeFeber, to reject the claims under § 102. Applicants filed a Request for Continuing Application on November 7, 2005, including a preliminary amendment. On January 20, 2006, the examiner rejected the claims again under the LeFeber patent. Applicants responded to the office action on April 12, 2006. On July 11, 2006, the examiner issued the final office action, rejecting the claims on new grounds, namely the Broussard patent.

Claim 1 recites that the band is divided into at least a first closed loop and a second closed loop. The meaning of the term "divided into" is ascertained by resort to the specification. In the specification at page 4, lines 18-20, the band is divided into closed loops by joining two points along the width of the band, such as by stitching or some other non-disengagable fastening technique. Thus, the term "divided into" as used in the claims, refers to sectioning off a portion of the band. Relatedly, the term "closed loop," used in all the claims, refers to one of the sectioned off parts of the band formed by dividing the band.

The Broussard patent does not disclose either of these limitations: it does not show a divided band, nor does it show closed loops formed by dividing the band. Instead, the Broussard patent discloses a band having holes cut into it to hold forward-facing penlights. Accordingly, Broussard does not disclose all the limitations of the claims of the present invention and therefore does not anticipate the claims. As such, the rejection is clearly erroneous.

In an advisory action issued over six months after the final rejection[2], the examiner rejected applicants' argument regarding the Broussard patent. The examiner observed that limitations from the specification are not read into the claims, citing *In re Van Geuns,* 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993), and that therefore the teaching in the specification does not clearly limit the manner in which the loops are formed and that loops may be formed by various other means, without changing the function of said loops.

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[2] The final rejection was mailed on July 11, 2006. On August 9, 2006, applicants filed a request for withdrawal of the final office action as premature in that the Broussard patent, a previously uncited reference, was relied upon for the rejection, and a request for reconsideration of the rejection. It was not until January 19, 2007, over six months after the final rejection and after appellants had filed their notice of appeal, that the advisory action issued.

Appellants agree that the claims are not limited in the specific method of forming loops. That was not the point, however, of looking at the specification. The appellants turned to the specification to explicate the meaning of the term "loop" as used in the claims. *Phillips v. AWH Corp.,* 415 F.3d 1303, 1315-17, 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005) *en banc* ("the specification necessarily informs the proper construction of the claims" and it is "appropriate . . . to rely heavily on the written description for guidance as to the meaning of claims."). The meaning of the term "loop," as used in the specification, is a gathered portion of the fabric band. The Broussard patent does not show any gathered portions in a fabric band. The Broussard patent shows only holes cut into a fabric band. *See,* Figs 1 and 2 of the Broussard patent.

The advisory action does not point to anything in the Broussard patent that shows, discloses or suggests the limitations of the claims. Accordingly, appellants maintain that the Broussard patent does not anticipate the claims.

Conclusion

In view of the foregoing, appellants respectfully submit that the application presents patentable subject matter as claimed, and requests that the claims be allowed to issue.

February 12, 2007

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Claims appendix

1. A device to secure medical tubing to a body comprising a circular one-piece fabric band having a length wherein the band is divided into at least a first closed loop and a second closed loop such that the band is composed of no more than two layers of fabric anywhere along the length, and wherein the first closed loop fits elastically around a portion of the body and the second closed loop is capable of receiving and holding medical tubing close to the body.

2. A device according to claim 1 wherein the portion of the body around which the first closed loop fits is a head.

3. A device according to claim 1 wherein the fabric band is covered with a soft, non-irritating material.

4. A device according to claim 1 wherein the fabric band is at least partially lined with a friction creating material.

5. A device according to claim 1 wherein the closed loops are formed by stitching.

6. A device to secure medical tubing to a body comprising a circular one-piece fabric band having a length wherein the band is divided into a first closed loop, a second closed loop and a third closed loop such that the band is composed of no more than two layers of fabric anywhere along the length, and wherein the first closed loop fits elastically around a portion of the body and the second and third closed loops are capable of receiving and holding medical tubing close to the body.

7. A device according to claim 6 wherein the portion of the body around which the first closed loop fits is a head.

8. A device according to claim 6 wherein the fabric band is covered with a soft, non-irritating material.

9. A device according to claim 6 wherein the fabric band is at least partially lined with a friction creating material.

10. A device according to claim 6 wherein the closed loops are formed by stitching.

11. A device to secure medical tubing to a body comprising a circular one piece fabric band having a length and a width wherein stitching along the width joins a first portion of the band to a second portion of the band, and joins a third portion of the band to a fourth portion of the band to form a first closed loop, a second closed loop and a third closed loop such that the band is composed of no more than two layers of fabric anywhere along the length, and wherein the first closed loop fits elastically around a portion of the body and the second and third closed loops are capable of receiving and holding medical tubing close to the body.

12. A device according to claim 11 wherein the portion of the body around which the first closed loop fits is a head.

13. A device according to claim 11 wherein the fabric band is covered with a soft, non-irritating material.

14. A device according to claim 11 wherein the fabric band is at least partially lined with a friction creating material.

Evidence appendix

Declaration of Terri Lee Mauer with attachment A, submitted by applicants on 5/11/05

Declaration of Venjiamin Ratner with photos 1-4, submitted by applicants on 5/11/05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Christine Carlucci and Gerard Carlucci

For: Medical Tubing Securing Device

Serial No.: 09/930,398

Filed: August 15, 2001

Group: 3761

Atty Docket: 262-801

DECLARATION

I, Terri Lee Maurer, hereby state:

1. I am a registered nurse and have been employed at Columbia Presbyterian Hospital since 1987. I have been with the neonatal intensive care unit (NICU) at the hospital since 1989.

2. The NICU generally has around 55 newborn patients in its care at any one time. These tiny patients range in age from the smallest of "preemies" (prematurely born infants) to two or three month old infants. One of the reasons for hospitalization of many of these babies is that they require respiratory care due to such conditions as a prematurity, underdeveloped lungs, collapsible airway, small lung volume, or muscle weakness.

3. Traditional treatment for many such patients has generally been intubation which involves the insertion of tubing into the infant's nose and down into the trachea. The tubing is attached to a ventilator which pushes a volume of air into the patient's lung at regular intervals. The ventilator thus "breathes" for the patient.

4. Intubation is an invasive and uncomfortable procedure. Moreover, many problems can arise with intubation such as bronchopulmonary dysplasia and

pneumonia. For these reasons, it has been the practice of the NICU at Columbia Presbyterian to provide respiratory support to our patients using a system known as CPAP, which stands for "continuous positive airway pressure." CPAP is an airway treatment which provides a slight positive pressure of air during inhalation to increase the volume of inspired air and to decrease the work of breathing. CPAP is administered by nose.

5. The most appropriate way to administer CPAP to infants is by the use of a nasal prong apparatus. A typical example of one such commercial product for delivering infant CPAP is the Hudson RCI Infant Nasal Prong CPAP cannula system shown in the attachment **A** to this declaration. Each system includes one cannula, one inspiratory and one expiratory elbow, two 4 ft. lengths of 10 mm I.D. corrugated tubing, one 4 ft. pressure monitoring line, one 22 mm to 10 mm humidifier adapter, one knit cap, and two 5 inch sections of Velcro securing tape. Two nasal prongs, which are attached to the cannula, are inserted into the nostrils. The cannula is attached via the corrugated tubing to a pressurized line so that a positive pressure of air flows into the nostril. The tubing is kept in place by looping velcro straps around the tubing and then attaching the velcro straps to a knit hat which is placed on the infant's head.

6. While the CPAP method works well to open the alveoli, i.e., the little air sacs in the lungs, it has always been a problem to position the cannula and tubing so that the nasal prongs do not shift out of the nostrils. The knit caps which are provided with the commercial products and to which the tubing is secured with Velcro straps generally do not stay in position without extra measures. As a consequence, the nursing staff has had to resort to a number of different strategies in order to secure the

apparatus so that the nasal prongs stay in the infant's nose where they will do their work. We have tried using safety pins to anchor the tubing to the caps. We have also used rubber bands or hospital tape to secure the hats and the tubes to the infant's head.

7. These measures have not been satisfactory because they often result in skin irritation and/or discomfort, which results in the infant moving its head more and causing more irritation and discomfort and possibly, dislodging the nasal probes. Even if there is no discomfort, infants often move anyway and cause the hat to fall off the head, which then causes the tubing to pull away. As the infant gets older, the amount of movement also increases, making the older infants more prone to equipment dislocation. It has been an ongoing problem.

8. I met Christine and Gerard Carlucci when their son Anthony was a patient at the NICU unit of Columbia Presbyterian. Anthony was receiving CPAP respiratory support and was experiencing the types of problems I describe. One day Mrs. Carlucci presented us with a device that they had made and asked us if it could be used for Anthony.

9. The device was a simple elastic terrycloth headband of the type used by athletes during exercise. Mrs. Carlucci had stitched the headband together in two places, thus dividing the one large loop into three smaller loops. The center loop fit over the crown of Anthony's head and rested just above his ears. We threaded the CPAP tubing through the loops over his ears and then placed the prongs in his nose.

10. We were very happy to see how well the Carlucci band worked. Because of the elasticity of the band and the fact that it fit below the widest part of the head, the

band stayed in place and did not shift when Anthony moved. The loops held the tubing in place and there was no pulling at the nasal prongs. The softness of the terrycloth was well-tolerated, unlike the velcro straps and adhesive tape that had been used with the commercial kit.

11. I have looked at US Patent 5,411,484 to Shattuck which shows a strap which is wrapped behind a patient's neck, the ends are secured with velcro onto the strap to create loops to hold an intubation tube in place. The loops exert opposing forces on the tube to keep it centered in the patient's mouth. I have never seen such a device used for infant CPAP administration and it does not appear that it would be an appropriate device for use with infants for several reasons. First, since two nasal prongs must be kept in place, one would need to use two Shattuck straps, increasing the likelihood of irritation of sensitive skin. Second, the Shattuck straps would need to be tightened around the infant's neck in order to hold the tubes in place. As a general rule, however, we strive to avoid putting anything, especially straps, around infants' necks for safety reasons. Third, the ends of the straps are equipped with velcro which can irritate sensitive infant skin very easily. Although I see that the velcro is placed on the side of the Shattuck strap which is not meant to touch the skin, it is not unusual for medical strapping to get twisted or disconnected. If such event occurred, then the rough velcro would be in a position to irritate the skin. Moreover, if the velcro became disconnected during use, it would cause the CPAP nasal prongs to shift from effective position.

12. The Carlucci band avoids all of the problems presented by the Shattuck strap. Only one Carlucci band is needed to keep both nasal prongs in place. The

Carlucci band goes around the sturdy skull, not the vulnerable neck. The Carlucci band is fabricated of a soft, non-irritating fabric, with no sharp or rough portions. Finally, the loops of the Carlucci bands are closed and cannot be opened, so the nasal probes cannot fall away from position.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

April 7, 2005

Terri Lee Maurer RNC

Terri Lee Maurer

HUDSON RCI
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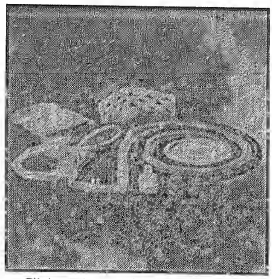
Cannulas, Masks, Tubing : Infant Nasal CPAP Cannulas

Infant Nasal Prong CPAP

The Hudson RCI infant nasal prong continuous positive airway pressure (CPAP) cannula system is designed to reduce trauma associated with the delivery of infant nasal CPAP. Hudson RCI CPAP prongs are available as a system for use with a water seal or spring loaded valve or as a set for use with any mechanical ventilator.



Click on image for larger picture

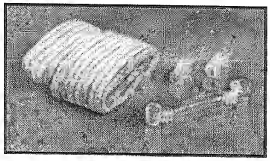
- Soft anatomically curved prongs minimize nasal septal necrosis
- Six prong sizes fit a full range of infants (see sizing chart below).
- Adjustable right-angle connector facilitates positioning of tubing to increase infant comfort
- Educational videotape available upon request
- Both systems and sets are individually packaged, 10 per case

Infant CPAP System

Each system (shown above) includes one cannula, one inspiratory and one expiratory elbow, two 4 ft. lengths of 10mm I.D. corrugated tubing, one 4 ft. pressure monitoring line, one 22mm to 10mm humidifier adapter, one knit cap and two 6 inch sections of Velcro securing tape.

Infant CPAP Sets

Sets are intended for use with mechanical ventilators and include one cannula, one inspiratory and one expiratory elbow connector, two 10mm to 7.5mm adapters, one knit cap and two 6 inch sections of Velcro securing tape (not shown in photo).



CPAP Cannula Sizing Chart & Ordering Information

Weight Range	Suggested Cannula Size	System Cat. No.	Set Cat. No
Less than 700 grams	0	1683	1690
700 grams to 1,250 grams	1	1685	1691
1,250 grams to 2,000 grams	2	1686	1692
2,000 grams to 3,000 grams	3	1687	1693

Over 3,000 grams	4	1688	1694
1 to 2 years of age	5	1689	1695

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For: Medical Tubing Securing Device

Serial No.: 09/930,398

Filed: August 15, 2001

Group: 3761

Atty Docket: 262-801

DECLARATION

I, Veniamin Ratner, M.D., hereby state:

1. I am a third year fellow in neonatal/prenatal medicine at Morgan Stanley Babies Hospital of Columbia University. I have been with this hospital for five years, the first two years of which were spent as a licensed pediatrician in the position of clinical instructor in neonatal medicine.

2. Many of my patients have respiratory issues. We treat many of these issues with the administration of continuous positive airway pressure (CPAP) through the nose. I am thus well familiar with the use of CPAP equipment, especially for neonates.

3. The equipment that is commercially provided for infant CPAP administration consists of, among other things, tubing, nasal prongs, velcro straps, and a knit hat. CPAP procedure involves providing a continuous stream of air which travels through the tubing to the nasal prongs which are fit into the infant's nostrils. In order to maintain the tubing in position, velcro straps are provided to attach the tubing to the knit hat on the infant's head. Attached as photos 1 and 2 are photographs of the commercial device being used on a premature infant.

4. A number of problems arise with the materials supplied for use with the CPAP apparatus. For one thing, the size of the hat supplied is always problematic. It is usually too big for the small kids and too small for the big kids. As can be seen in photo 1, the hat easily slips off the head of tiny premature infants.

5. Another more difficult problem that arises is that even when the hat fits the head, it does not have a good enough grip to stay on the head when the infant moves around. As the infant grows, the infant becomes much more mobile. While increased movement is generally a sign of increasing health, movement also can cause the knit hat to slide off the infant's head, which results in dislodging the nasal probes from the infant's nose.

6. We thus have employed a number of measures besides velcro straps to try to keep the nasal prongs in place, including using safety pins, rubber bands and tape. Shown in photos 1 and 2 is a CPAP apparatus attached by pinning two safety pins to the hat on either side of the oxygen tubing. We then twist a rubber band around and through the pins to fasten the tubing to the hat. While these measures are somewhat helpful, they are not usually altogether satisfactory because the hat still slips off the head easily.

7. One day, Christine Carlucci, the mother of one of my patients, after observing these problems occurring during her son's CPAP treatments, asked me if we could try a device that she had made. It was an elastic terrycloth headband that had been divided into three loops. The middle loop fit over the infant's head and the side loops held the CPAP tubing in place close to the head. It was soft and non-irritating, and the elastic hold on the head was gentle, yet unmoving and consistent. It appeared

to be a safe device and we tried it. The headband worked extremely well holding the tubing in place. It did not slip off the head when the infant moved and it appeared to be very comfortable for the infant. Attached photos 3 and 4 show the device in use.

8. I was very impressed with the effectiveness of the Carlucci headband. There were a great many advantages to it over the knit hat and other attachment measures that we had been using. The relatively large surface area of the band made it easy to manipulate around the heads of our delicate patients. It was easily adjustable by size. It did not interfere with the CPAP set-up. It also preserved the mobility of the infants, especially that of the older neonates weighing between five to seven pounds.

9. We have since been using the Carlucci headband quite successfully for our neonate CPAP patients. The medical staff and the parents love it because the infants are obviously comfortable and are receiving the full benefits of their CPAP treatments. We feel that the Carlucci headband is a great advantage over the devices currently on the market for infant CPAP.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

May 10, 2005

V. Ratner

Veniamin Ratner, M.D.

Photo 1: CPAP apparatus on premature infant. Safety pins and rubber bands secure tubes to hat

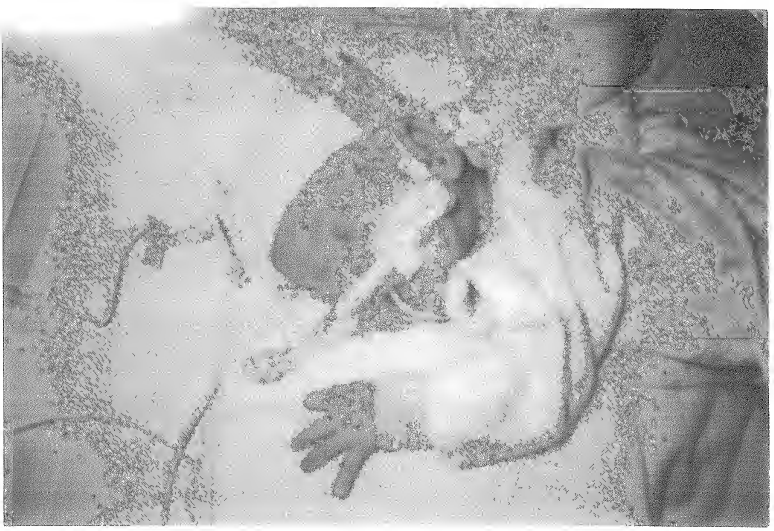

Photo 2: CPAP apparatus on premature infant. Safety pins and rubber bands hold tubes to hat

Photo 3: CPAP held on infant's head using Carlucci device

Photo 4: CPAP held on infant's head using Carlucci device